REMARKS

Claims 44-51, 62-64, 67-72, 74 and 78-89 are pending.

For the Examiner's convenience, the remainder of this Amendment is set forth under appropriate headings, in the order in which the issues were raised in the Office Action.

Rejection of Claims under 35 U.S.C. 112, first paragraph

The Examiner rejected Claims 44-51, 62-64, 69-74 and 78-89, stating that the specification did not provide guidance to make the constructs used in the experiments submitted by Declaration, and that the experiments could not be extrapolated to the human *in vivo* environment.

The constructs described in the Declaration under 37 C.F.R. 1.132 of Dr. Harriet L. Robinson filed on February 28, 1996 (the "first Declaration") are essentially the same as those described in the Specification in Example 13, pages 53 through 55. For example, it can be seen that the SIV239.dpol insert that was used in constructs described in the first Declaration, shown in Figure 1B of the Appendix to the first Declaration, is the same as the SIV239.dpol insert shown in Figure 16B of the Specification. Therefore, Applicants have shown use of the relevant constructs to produce an immune response which protected animals, partially or totally, from the manifestations of infection caused by the infectious agent, as four monkeys in the multiple route group were protected against manifestations of disease throughout the trial described in the first declaration.

Furthermore, the SIV constructs used in the trial described in the first Declaration, and described in the Specification, are comparable to the HIV constructs described in the Specification in Example 11, pages 45-49.: both the SIV constructs and the HIV constructs encode specific, correlative portions of proteins from their respective immunodeficiency viruses. For example, the SIV239.dpol construct described in the first Declaration had a defective pol gene, and expressed env proteins. Similarly, pCMV/HIV-1-NL4-3.dpol constructs described at page 46 of the Specification were designed to express env but not pol proteins (because of a defective pol gene).

Furthermore, the HIV constructs described in the Specification showed the ability to raise antibody titers as well as cytotoxic T-cell activity in mice, as described in the Specification in Example 12 (pages 49-53). In view of this immune response generated by the HIV constructs, and in view of the similarity between the HIV constructs and the SIV constructs, one of ordinary

skill in the art could reasonably assume that the HIV constructs could have a protective effect that was similar to the protective effect shown in relation to the SIV constructs.

Rejection of Claims under 35 U.S.C. 102(e)

The Examiner rejected Claims 44, 51, 81, 83 and 89 as being anticipated by Wolff *et al.*, U.S. patent 5,693,622, stating that Wolff *et al.* describe intravenous injection of mice with a nucleic acid vaccine encoding the nef gene and citing Column 28, Example 9.

The Claims are drawn to methods of immunizing a mammal against an immunodeficiency virus, comprising administering to the mammal a DNA transcription unit comprising DNA encoding an antigen of the immunodeficiency virus, operatively linked to DNA which is a promoter.

Wolff *et al.* describe vaccination of mice with NEF mRNA (messenger ribonucleic acid). As described in Example 9 (Column 28, particularly lines 23-31), NEF mRNA was prepared, incorporated into a liposome preparation, and injected into the mice. Wolff *et al.* do not describe vaccination with deoxyribonucleic acid (DNA). Therefore, the teachings of Wolff *et al.* do not anticipate the current methods of immunizing a mammal by administering a DNA transcription unit comprising deoxyribonucleic acid encoding an antigen, operatively linked to deoxyribonucleic acid which is a promoter.

The Examiner also set forth a rejection of claims as being anticipated by Felgner *et al.*, U.S. patent 5,703,055, stating that Felgner *et al.* describe intravenous injection of mice with a nucleic acid vaccine encoding the nef gene and citing Column 31, example 9. The Office Action does not specify which claims are rejected as being anticipated by Felgner *et al.* Because the teachings of Wolff *et al.* and Felgner *et al.* that are cited by the Examiner are identical, word for word, Applicants' Attorney has assumed for the purposes of this Amendment that the rejection under Felgner *et al.* is directed towards the same claims as those that were rejected as being anticipated by Wolff *et al.* (i.e., Claims 44, 51, 81, 83 and 89).

The teachings of Felgner *et al.*, like those of Wolff *et al.*, describe vaccination of mice with NEF mRNA (messenger ribonucleic acid), and do not describe vaccination with deoxyribonucleic acid (DNA). Therefore, the teachings of Felgner *et al.* do not anticipate the current methods of immunizing a mammal by administering a DNA transcription unit comprising deoxyribonucleic acid encoding an antigen, operatively linked to deoxyribonucleic acid which is a promoter.

CONCLUSION

In view of the discussion presented above, the claims are in condition for allowance. Therefore, Applicant's Attorney respectfully requests that the Examiner reconsider and withdraw all the rejections.

If the Examiner feels that a telephone conversation would expedite prosecution, the Examiner is invited to call Elizabeth W. Mata at (915) 845-3558. If Elizabeth W. Mata cannot be reached, the Examiner is invited to call Patricia Granahan at (781) 861-6240.

Respectfully submitted,

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